EXHIBIT F

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 1629
THIS DOCUMENT RELATES TO: BULGER v. PFIZER, et al., 07-11426-PBS	Master File No. 04-10981
SMITH v. PFIZER, et al, 05-CV-11515-PBS	Judge Patti B. Saris Magistrate Leo T. Sorokin

DEPOSITION OF ALEXANDER RUGGIERI, taken at 999 Enchanted Way, Board Room 3, Simi Valley, California, commencing at 9:10 A.M., Friday, December 5, 2008, before Kathleen E. Barney, CSR #5698.

Job No. 183324

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DAVID WEST, Videographer

THE VIDEOGRAPHER: Good morning. We are on the record at 9:10 a.m. on December 5, 2008. My name is David West and I represent Veritext National Deposition and Litigation Services. This deposition is being held at the Grand Vista Hotel at 999 Enchanted Way, Board Room No. 3, Simi Valley, California. The case is entitled In Re Neurontin Marketing Sales Practices and Products Liability Litigation, MDL Docket No. 1629. The deponent is Dr. Alexander Ruggieri. 09:11

Would all counsel please identify themselves for the record, after which our court reporter, Kathy Barney of Veritext, will swear in the witness and we'll begin.

MR. ALTMAN: This is Keith Altman on behalf of the Products Liability plaintiffs and also the Crone plaintiffs in the case of Crone versus Pfizer. 09:11

MR. BARNES: Richard Barnes on behalf of Pfizer and Parke-Davis and in MDL and in Crone.

MR. WASICKO: This is Michael Wasicko from Goodell DeVries on behalf of the Pfizer defendants. 09:12

MS. BERMAN: This is Kendra Berman on behalf of Dr. Jennings in the Crone matter.

THE VIDEOGRAPHER: Thank you.

Ms. Court Reporter. 09:12

ALEXANDER RUGGIERI,
a witness herein, having been duly sworn, was examined and testified as follows:

MR. ALTMAN: Before we begin, I just want to put one thing on the record. 09:12

Recently, in the last few days, this case was noticed in the California State Court case of Crone versus Pfizer. Under California rules, we are not -- do not have the same time limitations as in the MDL case. I'll do everything in my power to conclude my examination by today, but in the event that I'm unable to, under the California rules I will hold the deposition open for follow-up questioning at a later date to be determined. 09:12 09:13

MR. BARNES: We don't agree with that, but we will talk about that at a later date, so -- we have a course of dealing and understanding in this case, but go ahead. I am very comfortable that you can complete his deposition within the time allotted. 09:13

MR. ALTMAN: I will do my best.

EXAMINATION

BY MR. ALTMAN:

Q. Dr. Ruggieri, how are you today? 09:13

don't always have the same number of placebo patients. You don't -- there might be denominator issues. So there are analyses which could perhaps make one feel more comfortable with that proposition, that there is a difference. And then some things by virtue of regulatory practice in approving a drug, so, for instance, you could have more deaths in a placebo group, but if you have one death in the treatment group, that is something that would -- is almost always included in the product label.

BY MR. ALTMAN:

Q. What does the term "suicidal" mean?

A. Suicidal to me is a very broad term that encompasses suicide gesture, suicide ideation, suicide -- actual suicide attempt. Injurious behavior. To me it means -- so if someone said, "This patient is suicidal," it could mean that they had either demonstrated or had the potential of demonstrating those concepts.

Q. Does it mean that they've completed suicide?

A. No. They would say the patient is dead from suicide. So if there is a corpse, then somebody committed suicide. When they say that, it usually means that -- it applies to a patient who is alive.

Q. So, in other words, does everybody who is --

under your definition of suicidal, does everybody who is suicidal actually commit suicide?

A. No, not necessarily.

Q. Do you have any idea what percent do actually commit suicide?

A. I'm not up on the statistics. I'm not a suicidologist.

Q. By the term "suicidologist," does that -- do you mean that there are people who spend their time studying these statistics and the --

A. Who study the epidemiology of suicide and have these numbers on the tip -- that what's I mean by that. But I know -- I know that -- I'm sorry. I wasn't finished answering.

As a clinician --

Q. You didn't let me finish my question.

MR. BARNES: Well, let's finish both.

THE WITNESS: Who do you want to finish first?

BY MR. ALTMAN:

Q. Go ahead. I think you were going to answer what I was going to ask anyway, so that's fine.

A. As a clinician, the term "suicidal" to me applies, A, to a live patient. And, number two, that it indicates that a patient is at risk for any one of

those things that I mentioned, including completed suicide.

Q. What does the term "suicide gesture" mean?

MR. BARNES: To him? His opinion on that? Go ahead.

MR. ALTMAN: Well, he has rendered an opinion on the --

MR. BARNES: Sure.

MR. ALTMAN: -- adequacy of the label, so --

THE WITNESS: Suicide gesture to me means, again, very broadly can mean any act, inclination, hint, verbal threat, explicit or implicit, that could suggest a risk for a suicide attempt.

BY MR. ALTMAN:

Q. Is that the same as suicidal ideation? Does it -- strike that.

Does that include suicidal ideation?

A. Yeah, I would include features or manifestations of the patient that would indicate suicidal ideation. Ideation means their thoughts and so those could be manifested in different ways in patients.

Q. Would everybody who -- would the term "suicide gesture" include suicide attempt?

A. I would imagine that some clinicians may

interpret it that way. The gesture -- gestures, in my mind, generally, you know, preclude the attempt. So you could prevent an attempt by identifying gestures.

Q. But if I understand what you said, a suicide gesture is not the same as a suicide attempt?

MR. BARNES: Objection. He said it could, but -- well, restate your answer.

THE WITNESS: It's -- this is my own, Alex Ruggieri, the physician, I don't know that there is any formal ontology or definitions that -- O-N-T-O-L-O-G-Y -- or definitions that show that -- that suicide attempt is a parent of suicide gesture or vice-versa, if suicide gesture is a parent of suicide attempt. Gestures -- a suicide attempt is an almost completed suicide, and some people may separate that. But suicide gesture could be technically a suicide attempt. So even if it's an attempt to scratch yourself with a dull knife, that could be interpreted as an attempt and could be interpreted as a gesture both. There is no formal line. I think for the clinician anything with S-U-I pretty much gets the message across.

BY MR. ALTMAN:

Q. Is -- does everybody who is -- has a suicide

gesture, do they all have suicide attempts?
A. Well, in some people's definition, a gesture may be equivalent to an attempt. In the example I just gave you.
Q. What about in your definition, though, is there a difference? 12:24
A. Again -- and it's just my own personal -- I'm not a suicidologist. There may be more formal terminologies around this. But a gesture to me -- well, first of all, suicidal kind of includes the whole gamut for me. And gesture, I wouldn't object if somebody stated that, you know, a gesture -- an attempt is a type of gesture. 12:24
Q. If somebody were to take a gun out of the drawer and put it on the table and look at it, would you consider that a suicide gesture? 12:25
A. It would depend on what the clinical state and background of that patient was, what their -- has been going on with them.
Q. If somebody had thoughts of suicide -- 12:25
A. Suicidal ideation?
Q. If somebody had suicidal ideation and went and took a gun out of the drawer and put it on the desk and sat there looking at it, would you consider that a suicide gesture? 12:25

MR. BARNES: Objection.
If you have an opinion.
THE WITNESS: Potentially. Again, it would depend on what other circumstances are going on with the patient. 12:25
BY MR. ALTMAN:
Q. Well, is that something more than suicidal ideation?
A. I'm sorry?
Q. Is that something more than suicidal ideation? 12:25
A. Is what something more than suicidal ideation?
Q. Taking a gun out of the drawer and sitting there and putting it on the desk and looking at it. 12:25
MR. BARNES: I'm going to object right now. He has not been offered as an expert on suicide per se or -- and so I think you're asking questions that would go more properly to Dr. Jacobs, who has been deposed in this case. So to the extent -- I'm objecting it's beyond the scope of his report. 12:26
If you can tie it in and let me know what the -- how it ties into his labeling opinion as to the actual conduct of a patient -- and we've not offered him in this area -- I'd be happy to entertain 12:26

it. But it's way beyond what he has been offered for.
MR. ALTMAN: You know, I think we've -- we don't need to go into so much of a thing, but he has commented on the adequacy of the label. 12:26
MR. BARNES: Correct.
MR. ALTMAN: Okay. And so this goes to the adequacy of the label, because we're talking about the terms that were used in the label and whether they are the same as what actually occurred. 12:26
MR. BARNES: That's not -- his testimony was that the word "suicidal" runs the whole gamut, it's a broad term. And suicide gesture can encompass suicide attempt, in some people's minds. In his mind, he gave you a definition. 12:26
Now, as to how a patient -- what is a clinical manifestation of whether there is a requisite attempt for a gesture -- or requisite intent for a gesture or an attempt, that's not his area that he has been offered on. And you're getting into specific clinical manifestations of suicide, and that is not what he is going to talk about. So -- 12:27
MR. ALTMAN: But -- well, here is my only point. In his report he claims that the labeling was adequate. 12:27

MR. BARNES: Correct.
MR. ALTMAN: And we're exploring whether the term "suicide gesture" and "suicidal" were adequate to describe what was going on. And you're questioning whether he is qualified to talk about those differences. So my point is -- 12:27
MR. BARNES: As a clinician, he is absolutely qualified to do that. And you're asking him now as to where he might draw the line as a clinician looking at a specific patient situation. And it has nothing to do with the label. It has to do with how he would view clinically a situation. And you've not even given him enough facts, so -- 12:27
MR. ALTMAN: Then how does he determine if the label is adequate with respect to those terms? 12:27
MR. BARNES: Why don't you ask him that question and he will tell you.
MR. ALTMAN: We'll come to his opinion and that's fine.
BY MR. ALTMAN: 12:28
Q. I think we said before not every suicidal event includes completed suicide, correct?
A. Correct.
Q. So the term "suicide" is more specific than the term "suicidal," correct? 12:28

Q. Okay. Does the FDA use spontaneous data to -- for signal detection purposes?
A. I don't think so. You'd have to ask, but my understanding is that the trend is moving away from that type of data. 16:14
Q. And what is your basis for that?
MR. BARNES: Let him finish his answer.
THE WITNESS: My basis for that is the Institute of Medicine Safety Report. The Scientific Advisory Committee report on the FDA. The FDA's own 16:15
initiatives with the Sentinel Network with the VA, with CNS to do signal detection in what the Institute of Medicine report calls large health care databases.
BY MR. ALTMAN:
Q. Does the World Health Organization use 16:15
spontaneous data for signal detection purposes?
A. I do not think they do.
Q. Are you familiar with the Uppsala Monitoring Center? U-P-P-S- --
A. Uppsala. Sweden. 16:15
MR. BARNES: U-P-P-S-A-L-A, I think. It's a city in Sweden.
THE WITNESS: No, I'm not familiar with that institute. However, I am familiar with the Swedish health care system and their collaboration in 16:16

creating large-scale health care -- longitudinal health care databases. It's a nationalized health care system, so they have capabilities to access that system very readily.
BY MR. ALTMAN: 16:16
Q. Does Pfizer conduct data mining activities?
A. At this time?
Q. At this time.
A. I would imagine they do, yes.
Q. Do you know when they started doing that? 16:16
A. No, I don't.
Q. Does Pfizer use spontaneous data for signal detection?
A. I believe they do.
Q. Do you think that's inappropriate for them 16:16
to do so?
A. No, I don't think it's inappropriate. I think you have to understand the limits of the data. My feeling about spontaneous data is that it helps you if it helps you, but it doesn't really get you 16:16
anywhere at the end of the day and that there are more reliable data sources to -- unfortunately, industry is -- doesn't have as ready access. So industry is constrained oftentimes with being stuck with the worst data source. 16:17

MR. BARNES: Are we done?
MR. ALTMAN: Not even close.
MR. BARNES: Are you getting tired?
MR. ALTMAN: Can't find what I'm looking for here. 16:17
BY MR. ALTMAN:
Q. When did -- was suicide a labeled event in the Neurontin label?
A. It was in the 1993 label.
Q. So if in Pfizer's opinion suicide was not 16:18
labeled, you would disagree with that?
A. Well, sorry, when you say "suicide" and when you say "labeled," because the label -- with respect to warnings, precautions, observed events, et cetera, what do you mean when you say "labeled"? In any of 16:19
those?
Q. Are you familiar with the regulatory definition of labeled versus unlabeled?
A. Yes.
Q. Okay. Was suicide a labeled event in the 16:19
1993 label?
A. I believe it was in the context of the definition of labeled versus unlabeled, because it was listed in adverse events observed.
Q. The term "suicide" was listed? 16:19

A. I didn't say that.
Q. Okay. So if Pfizer disagrees with you that suicide was labeled, you would disagree with them?
A. I'm dealing with it from the standpoint of a clinician and there was sufficient labeling around 16:20
the notion of suicidal behavior, suicide or suicide. And we -- this label -- this regulatory definition of labeled, labeled, unlabeled, I don't think there is a discreet labeled, unlabeled definition. That's a term that's -- unfortunately means -- can mean 16:20
different things in different contexts.
Q. Okay. So if Pfizer considered suicide to be unlabeled from a regulatory perspective, then they were wrong?
A. No, I did not say that. I need to know what 16:20
Pfizer means by unlabeled versus labeled.
Q. Well, let's -- we're going to come back to this, but one of the things I want to clarify --
A. The concept of suicide was in the '93 label, was encompassed in that. 16:21
Q. So from a regulatory perspective, the company should have considered reports of suicide to have been labeled events?
A. No. Again, this term -- there is no strict definition of labeled versus unlabeled. In fact, one 16:21

of the challenges that when conducting -- when collecting information on spontaneous adverse events is the extrapolation of what a -- is being presented in the adverse event report to clinical concepts that are in the label. Now, there are notions about 16:21
labeled versus unlabeled in the core data sheets. I mean, this word is very ambiguous and you need to define the context for me. So I'm not declaring anybody wrong here, especially with a word that has got variated meanings depending on context. 16:21

Q. All right. Let's change the words to expected versus unexpected.

A. Okay.

Q. Do those have a regulatory definition?

A. Yes. But it's not -- it still doesn't get 16:22
you -- it's not completely precise.

Q. But do they have a regulatory definition?

A. No.

Q. Okay. Does the company have to report spontaneous adverse events differently depending 16:22
whether they're expected or unexpected?

A. Yes.

Q. Okay. How does the company know whether -- how does the company determine whether something is expected or unexpected? 16:22

A. Like I said, as I just explained to you that there are clinical concepts which have correspondence to but may not be precisely mapped to a given adverse event as described in the label. So that's where many times a company may actually call it unexpected, 16:22
even though it seems to have a semantic relationship or conceptual relationship to an entity. And it could be because of some more finer-grained issues. This is something we encountered all the time in deciding it's not a -- there's no scalpel definition 16:23
that let's you know one way or the other.

Q. Do you know whether Pfizer considered suicide to be unexpected in the time period, lets's say, from 1994 to 2000?

MR. BARNES: If you know. 16:23

THE WITNESS: I don't know.

BY MR. ALTMAN:

Q. And one of the things we've been -- I want to clarify. You say that you offer opinions regarding Pfizer's conduct, but you do not mention 16:23
Warner-Lambert and Parke-Davis. Are you including those entities under Pfizer's conduct or do you not have opinions on Parke-Davis and Warner-Lambert?

A. Everything that I've based on Pfizer's conduct has been based on what I've seen in the 16:23

labels, what I've seen in Mr. Pacella's testimony. Those have been -- and the testimony from other people from Pfizer. That's what my testimony is based on.

Q. Do your opinions apply to Parke-Davis and 16:24
Warner-Lambert in the period of time before Pfizer acquired Parke-Davis and Warner-Lambert?

MR. BARNES: Which opinions are you referring to? He has two reports and he has talked about labeling going back to pre-approval. So you 16:24
should be very direct rather than a broad question, ask specifically, because they are spelled out in his report and --

BY MR. ALTMAN:

Q. Why don't we go to page 1 of your report. 16:24

MR. BARNES: Which one?

BY MR. ALTMAN:

Q. Of your supplemental report.

MR. BARNES: 14.

THE WITNESS: Page 1? 16:24

BY MR. ALTMAN:

Q. Of Exhibit 14. About the third or fourth sentence.

A. On page 1 or --

Q. On page 1. You say: 16:25

"I've also offered opinions regarding Pfizer's conduct in the development, testing and labeling of Neurontin."

Do those opinions only apply to Pfizer's 16:25
conduct or do they include Parke-Davis and Warner-Lambert?

A. To the extent that the testimony and the sources that I referred to represent what happened with Warner-Lambert, then they do. 16:25

Q. On page 2, second paragraph, you state:

"All evidence that I have reviewed in this case neither suggests nor supports a causal relationship of Neurontin to 16:26
suicide, suicidal behavior, suicidal ideation and clinical states related to suicidality."

Correct?

A. Correct. 16:26

Q. What does the term "clinical states related to suicidality" mean, as you use it here?

A. That could mean suicide gestures. It could mean suicide ideation. Or variations of the such related to suicidality. The gestures, thoughts, 16:27